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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/585,915

11/12/2008

Ning Hu

01992.001US2

1645

53684 7590 07/06/2011
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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

07/06/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,915	Applicant(s) HU ET AL.	
	Examiner GOLLAMUDI S. KISHORE	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,9,12,14,15,17,18,22,26,37 and 42 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,5,9,12,14,15,17,18,22,26 and 37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11-2-06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims included in the prosecution are 1, 5, 9, 12, 14-15, 17-18, 22, 26, 37 and 42.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 5, 9, 12, 14, 17, 18, 22, 26, 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Durr et al (Eur. Journal of Pharmaceutics and Biopharmaceutics, 1994) of record.

Durr discloses liposomes containing soya phosphatidylcholine and either DMPG or soya phosphatidic acid. The sizes of the liposomes are less than 100 nm (pages 149 and 150).

3. Claims 1, 5, 9, 12, 15, 17, 18, 22, 26, 37 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 697 214 of record.

EP discloses liposomes with a mean particle sizes of less than 100 and containing egg phosphatidylcholine and either phosphatidylglycerol or phosphatidic acid and cyclosporin. The phospholipid to cyclosporin ratio is 28:1 (Abstract, page 4, lines 9-14; Examples and claims).

3. Claims 1, 5, 9, 12, 17, 18, 22, 26, 37 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/13053 of record

WO discloses liposomal preparations containing phosphatidylcholine, a negatively charged phospholipid and Taxane. (Abstract and Example 1). Although WO does not specifically teach the mean particle sizes of the liposomes to be less than 100, since it teaches passing the liposomes through 0.1 micron filters, particles of less than 100 is implicit.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 15 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durr by itself or in view of EP both cited above.

The teachings of Durr have been discussed above. Durr does not teach the use of Egg PC. However, in the absence of showing the criticality, it is deemed obvious to one of ordinary skill in the art with a reasonable expectation of success to use Egg PC since EP teaches the routine practice of using Egg PC in liposomal formulations. Although Durr does not teach claimed ratios of the phospholipid to the drug, since the amount of drug depends upon the condition to be treated, it is deemed obvious to one of ordinary skill in the art to manipulate the amounts especially in view of the teachings of the claimed ratios by EP.

The reference of Forssen (6,120,800) which teaches anionic liposomes of less than 100 nm is cited as interest.

Art Unit: 1612

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GOLLAMUDI S. KISHORE whose telephone number is (571)272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612

GSK